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## NOTICE OF ALLOWANCE AND FEE(S) DUE

22798 7590 05/09/2008

QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C.  
P O BOX 458  
ALAMEDA, CA 94501

EXAMINER

GEBREYESUS, KAGNEW H

ART UNIT

PAPER NUMBER

1656

DATE MAILED: 05/09/2008

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/530,421

04/05/2005

Peter G. Schultz

54A-000170US

6734

TITLE OF INVENTION: SITE SPECIFIC INCORPORATION OF KETO AMINO ACIDS INTO PROTEINS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$720	\$300	\$0	\$1020	08/11/2008

**THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.**

**THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.**

### HOW TO REPLY TO THIS NOTICE:

#### I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

**IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.**

# **PART B - FEE(S) TRANSMITTAL**

**Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE  
Commissioner for Patents  
P.O. Box 1450  
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or Fax (571)-273-2885**

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

22798 7590 05/09/2008

QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C.  
P O BOX 458  
ALAMEDA, CA 94501

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

## **Certificate of Mailing or Transmission**

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/530,421 04/05/2005 Peter G. Schultz 54A-000170US 6734

TITLE OF INVENTION: SITE SPECIFIC INCORPORATION OF KETO AMINO ACIDS INTO PROTEINS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
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nonprovisional YES \$720 \$300 \$0 \$1020 08/11/2008

EXAMINER	ART UNIT	CLASS-SUBCLASS
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GEBREYESUS, KAGNEW H 1656 435-183000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) the names of up to 3 registered patent attorneys or agents OR, alternatively, 1 \_\_\_\_\_

(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 \_\_\_\_\_

3 \_\_\_\_\_

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee  
☐ Publication Fee (No small entity discount permitted)  
☐ Advance Order - # of Copies \_\_\_\_\_

4b. Payment of Fee(s); (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.  
☐ Payment by credit card. Form PTO-2038 is attached.  
☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number \_\_\_\_\_ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature \_\_\_\_\_

Date \_\_\_\_\_

Typed or printed name \_\_\_\_\_

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This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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10/530,421	04/05/2005	Peter G. Schultz	54A-000170US	6734

22798 7590 05/09/2008

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EXAMINER

GEBREYESUS, KAGNEW H

ART UNIT

PAPER NUMBER

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DATE MAILED: 05/09/2008

## Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 144 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 144 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

**Notice of Allowability**

Application No.

10/530,421

Applicant(s)

SCHULTZ ET AL.

Examiner

KAGNEW H. GEBREYESUS

Art Unit

1656

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed on 2/19/2008.
2. ☒ The allowed claim(s) is/are 1, 3-10 and 12-17.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of the:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).  
\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.  
(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached  
1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.  
(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.  
**Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |  |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Notice of Informal Patent Application                      |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br>Paper No./Mail Date _____    | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                    |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance   |
|  | 9. <input type="checkbox"/> Other _____.   |

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### **DETAILED ACTION**

Applicant's response on February 19, 2008 to the Office Action dated August 27, 2007 is acknowledged. Applicants have amended claims 1, 2, 9, 10, 15-17.

Claims 18 and 19 remain without prejudice. Claims 1-10, 12-27 are pending and are present for examination.

#### ***Withdrawn Objection - Specification***

The specification was objected to for unclear incorporation by reference to a related case by attorney docket number. Applicants have provided an amendment to the specification by using the patent Application Publication number. This objection is withdrawn.

#### ***Withdrawn - Claim Objections***

Claims 1-10, 12-17 were objected to because of the following informalities: These claims contain non-elected subject matter because they include SEQ ID NO: 19 and 20. Applicants have amended the claims to exclude these non-elected species, thus the objection is withdrawn.

#### ***Withdrawn - Claim Rejections - 35 USC § 102***

Claims 1-10, 12-16 were rejected under 35 U.S.C. 102(e) as being anticipated by US 7,045,337 B2 (Schultz et al). However no specific structure of an ORS identical to SEQ ID NO: 18 or a variant that is 90% identical thereto is disclosed in Schultz et al's. Therefore following the claim amendments and in view In Re Duel, the rejection of claims 1-10, 12-16 is withdrawn.

***Withdrawn -Double Patenting***

Applicants have filed a terminal disclaimer with regards to application U.S. Patent No. US 6,927,042 B2 (Schultz et al). Therefore the rejection has been withdrawn.

**EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Attorney Gary Baker on April 21, 2008.

Claim 1 (Presently amended) A composition comprising an orthogonal aminoacyl-tRNA synthetase (O-RS), wherein the O-RS preferentially aminoacylates an O-tRNA with p-acetyl-L-phenylalanine; and, wherein the O-RS comprises an amino acid sequence of SEQ ID NO: 18 or a conservative variation thereof comprising at least ~~80%~~ 90% sequence identity with SEQ ID NO: 18; and, wherein the ORS further comprises an Ala or Leu at position corresponding to position 32, or comprises Gly at a position corresponding to position 158 compared to wild type tyrosyl tRNA synthetase from *Methylococcus jannaschii*.

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Cancel claim 2.

Claim 9 (Presently amended) A cell comprising a translation system, wherein the translation system comprises:

an orthogonal tRNA (O-tRNA);

an orthogonal aminoacyl-tRNA synthetase (O-RS); and,

p-acetyl-L-phenylalanine;

wherein the O-RS preferentially aminoacylates an O-tRNA with p-acetyl-L-phenylalanine; wherein the O-RS comprises [an] the amino acid sequence ~~selected from~~ of SEQ ID NO: 18 or a conservative variation thereof comprising at least ~~80%~~ 90% sequence identity with SEQ ID NO: 18; and, comprising Ala or Leu at position corresponding to position 32, or comprising Gly at a position corresponding to position 158 compared to wild type tyrosyl tRNA synthetase from *Methylococcus jannaschii*.

Claim 15 (Presently amended) An E. coli cell comprising :

an orthogonal tRNA (O-tRNA);

an orthogonal aminoacyl-tRNA synthetase (O-RS);

wherein the O-RS preferentially aminoacylates the O-tRNA with p-acetyl-L-phenylalanine; wherein the O-RS comprises [an] the amino acid sequence ~~selected from~~ of SEQ ID NO: 18 or a conservative variation thereof comprising at least ~~80%~~ 90% sequence identity with SEQ ID NO: 18; and, comprising Ala or Leu at position

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corresponding to position 32, or comprising Gly at a position corresponding to position 158 compared to wild type tyrosyl tRNA synthetase from *Methylococcus jannaschii* ;

p-acetyl-L-phenylalanine; and,

a nucleic acid that comprises a polynucleotide that encodes a polypeptide of interest, wherein the polynucleotide comprises at least one selector codon that is recognized by the O-tRNA,

Claim 17 (Presently amended) An artificial and isolated polypeptide comprising ~~any one of~~ SEQ ID NO: [. ] 18.

Cancel claims 18-27.

### REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance:

A composition or a cell comprising the orthogonal tRNA synthetase structure of SEQ ID NO: 18 and the specific variants comprising 90% sequence identity to SEQ ID NO: 18, the specific O-tRNA of SEQ ID NO: 21 that can be used to incorporate the unnatural amino acid p-acetyl-L-phenylalanine is not disclosed in the prior art. The closest prior art is the disclosure by Schultz et al (US . 7,045,337 B2). Schultz et al teaches a cell comprising an ORS that aminoacylates an OtRNA with p-acetyl-L-phenylalanine (claim 8). However no specific structure for the ORS that preferentially aminoacylates an O-tRNA with p-acetyl-L-phenylalanine is disclosed. Therefore a composition comprising the specific orthogonal tRNA



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synthetase of SEQ ID NO: 18 or variants having 90% identity to SEQ ID NO: 18 is not anticipated by the prior art in view of In Re Duel.

**Conclusion:**

Following the amendments claims 1, 3-10, 12-17 are allowed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAGNEW H. GEBREYESUS whose telephone number is (571)272-2937. The examiner can normally be reached on 8:30am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kagnew H Gebreyesus PhD

/Robert B Mondesi/

Application/Control Number: 10/530,421

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Examiner  
Art Unit 1656  
4/23/08

Primary Examiner, Art Unit 1652